

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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CENTRAL RABBINICAL CONGRESS OF THE USA &  
CANADA, AGUDATH ISRAEL OF AMERICA,  
INTERNATIONAL BRIS ASSOCIATION, RABBI  
SAMUEL BLUM, RABBI AHARON LEIMAN, and  
RABBI SHLOIME EICHENSTEIN,

**DECLARATION OF DR.  
THOMAS FARLEY, M.D.,  
M.P.H.**

Plaintiffs,

12 Civ. 7590 (NRB)

-against-

ECF Case

NEW YORK CITY DEPARTMENT OF HEALTH AND  
MENTAL HYGIENE, NEW YORK CITY BOARD OF  
HEALTH, and DR. THOMAS FARLEY in his official  
capacity as Commissioner of the New York City  
Department of Health and Mental Hygiene,

Defendants.

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**THOMAS FARLEY, M.D., M.P.H.**, a physician authorized by law to practice  
medicine in the State of New York, declares the truth of the following under penalty of perjury,  
pursuant to 28 U.S.C. §1746:

1. I am the Commissioner of the New York City Department of Health and  
Mental Hygiene ("DOHMH") and Chair of the New York City Board of Health. I served as a  
Senior Advisor to former DOHMH Commissioner Thomas Frieden in 2007 and 2008.  
Immediately prior to becoming the Commissioner of DOHMH, I was chair of the Department of  
Community Health Sciences at the Tulane University School of Public Health and Tropical  
Medicine. I received my Medical Degree ("M.D") and Masters of Public Health ("M.P.H.")  
degree from Tulane University.

2. I was trained as a pediatrician, and served in the Epidemic Intelligence  
Service of the national Centers for Disease Control ("CDC") and worked for the CDC and

Louisiana Office of Public Health from 1989 to 2000. During that time, I directed programs to control various infectious diseases.

3. I have conducted research and published articles on a wide range of topics, including Legionnaires' disease, prevention of HIV and sexually transmitted diseases, infant mortality, and obesity. I am co-author of "Prescription for a Healthy Nation" (Beacon Press).

4. This declaration is submitted in opposition to plaintiffs' motion for a preliminary injunction seeking to enjoin the implementation of the recent amendment to New York City Health Code ("Health Code") § 181.21, requiring consent for direct oral suction as part of a circumcision. The facts herein are based on DOHMH records, conversations I have had with DOHMH employees and other employees of the City of New York, and my personal knowledge.

5. This declaration will address key public health information about herpes simplex virus ("HSV") infection in neonates ("neonatal herpes"), and cases of neonatal herpes associated with direct oral suction performed during ritual circumcision that were reported to DOHMH. I will describe the DOHMH case investigations and findings, relevant medical and scientific facts about herpes viruses, and the data and statistics that the DOHMH used to examine the relationship between direct oral suction and neonatal herpes. I will also explain how a team of DOHMH physicians (including pediatricians, infectious disease experts, and public health leaders), and epidemiologists, collected and interpreted the information on individual cases, consulted with nationally recognized herpes experts, and determined that direct oral suction performed during ritual circumcision can and has transmitted herpes to newborns.

6. It is the mandate of the DOHMH to protect the health of New Yorkers, and to that end, the DOHMH has undertaken efforts to educate the public and work with religious Jewish communities about HSV infection associated with direct oral suction. I will

describe those efforts, and the background leading up to the challenged rule. I will also discuss how DOHMH has received complaints from parents whose infants underwent direct oral suction during their circumcision without their knowledge.

#### **Key Facts About Herpes Simplex Viruses**

7. The human mouth is filled with micro-organisms, including bacteria and viruses such as herpes simplex virus (HSV). In fact, human bites are considered to have a very high risk for infection – an even higher risk than animal bites. The mouth is also considered a “dirty” site by surgeons because it cannot be sterilized. For this reason, no surgeon would ever place his or her mouth directly on an open surgical wound.

8. HSV is one type of virus which is commonly found in the mouth of adults. Herpes simplex viruses have several key characteristics. They: (1) establish infection in the nervous system; (2) cause lifelong infection which cannot be cured; (3) may remain inactive (“dormant”) for long periods; and, (4) may cause shedding of infectious virus particles at any point after a person becomes infected, even when the person is not exhibiting any symptoms of the virus. See publications of Miller C, Danaher R., “Asymptomatic Shedding of Herpes Simplex Virus (HSV) in the Oral Cavity,” *Oral Surgery Oral Med. Oral Pathol Oral Radiol Endod.* (2008); and Wald A, Zeh J, Selke S, Warren T, Ryncarz AJ, Ashley R, Krieger JN, Corey L., “Reactivation of Genital Herpes Simplex Virus Type 2 Infection in Asymptomatic Seropositive Persons,” *The New England Journal of Medicine* (2000), collectively annexed hereto as Exhibit “A.” There are two kinds of herpes simplex virus: HSV type 1 (“HSV-1”) and HSV type 2 (“HSV-2”). Oral herpes infection generally is caused by HSV-1 and genital herpes is generally caused by HSV-2. Because HSV-1 can be transmitted from the mouth to the

genitals, however, some cases of genital herpes infection are caused by HSV-1.<sup>1</sup> Most adults with oral or genital herpes infections have no symptoms and many do not know that they are even infected.

9. There are different ways to confirm HSV infection. One way is to test the blood for antibody to HSV. Antibodies are proteins produced by the body's immune system when it recognizes a foreign "agent" (such as bacteria or virus) in the body – antibodies are highly specific to the invading "agent." The presence of antibody in a person's blood indicates that person became infected with HSV at some point in the past and, therefore, is capable of spreading the infection to others even if he or she has no symptoms. Other tests (such as culture) look for the actual virus, rather than antibody. However, HSV virus is often difficult to find because infected people are not always shedding it; and periods of viral shedding are intermittent and unpredictable. In the case of oral HSV-1 infection, it can take many weeks of periodic sampling to find virus. See Miller publication, Exhibit "A." When actual virus is detected, not all laboratories additionally test to show whether the detected virus is type 1 or type 2. If typing has not been done, detected virus is described as "untyped HSV."

10. HSV infection does not usually cause symptoms, but if a person has physical signs of infection, they most commonly include clusters of small, painful blisters that appear on the skin at the point where virus was originally introduced, which is usually on the lips

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<sup>1</sup> HSV-1 can be transmitted from the mouth of an infected person to the genitals of another person. For sample publications reporting this, see, Lafferty WE, Downey L, Celum C, Wald A., "Herpes Simplex Virus Type 1 as a Cause of Genital Herpes: Impact on Surveillance and Prevention," *Journal of Infectious Disease* (2000), at 1454-7; and Cherpes TL, Meyn LA, Hillier SL, "Cunnilingus and Vaginal Intercourse Are Risk Factors for Herpes Simplex Virus Type 1 Acquisition in Women," *Sexually Transmitted Diseases* (2005), at 84-89. Indeed, because of orogenital sexual contact, a large and increasing proportion of genital herpes in the US is due to HSV-1. For another reference, see Roberts CM, Pfister JR., "Increasing Proportion of HSV-1 As a Cause of Genital Herpes Infection in College Students."

("oral herpes") or genitals ("genital herpes"). People who have these signs may experience multiple, recurrent outbreaks of painful blisters throughout their lives. Oral herpes infection is extremely common in the adult population of the United States. Approximately 60% of US adults are infected with HSV-1. See Xu F, Sternberg MR, Kottiri BJ, McQuillan GM, Lee FK, Nahmias AJ, Berman SM, Markowitz LE., "Trends in Herpes Simplex Virus Type 1 and Type 2 Seroprevalence in the United States," *Journal of the American Medical Ass'n*, (2006), annexed hereto as Exhibit "B." Because the presence of antibody to HSV-1 in the blood indicates infection, blood specimens can be used to measure the proportion of a population which is infected. In New York City, 73% of all adults (and 73% of women of child-bearing age) have HSV-1 virus infection. See DOHMH, "New York City Health and Nutrition Examination Survey" 2004 (custom table accessed July 27, 2012), annexed hereto as Exhibit "C." HSV can be transmitted from infected people even when they do not have any symptoms. This helps to explain how HSV infections have become so common in the general population. Herpes infections become more common with age.

#### **How Herpes Viruses Are Transmitted**

11. HSV is transmitted when an uninfected person comes into contact with virus present in the saliva or genital secretions of an infected person. Infection occurs at the site of contact, and is more likely to occur if there is a break in the skin. Characteristic blisters, may appear soon after at the point of initial contact. HSV virus travels up the sensory nerve supplying that section of skin where the initial contact occurred, and establishes permanent infection in that nerve, and (sometimes) in nerves that are adjacent at the level of the spinal cord. Because the skin on the body is divided up into areas ("dermatomes") served mainly by a single nerve the pattern of herpes blisters on the skin can show where infection was introduced. A copy

of a Dermatome Diagram is annexed hereto as Exhibit "D." Blisters may also appear on other areas of skin supplied by the same sensory nerve (related dermatomes).

12. The genitals are served by sacral nerve 2 (the penis) and sacral nerve 3 (the scrotum). Those nerves also serve areas of skin on the buttocks, and down the length of the leg to the ankle. If an HSV infection is introduced at the genitals, blisters may appear on the genitals, and also in these other areas. If infection disseminates in the blood, herpes blisters may appear on other, more distant places on the body, as well.

#### **Transmission of HSV to Newborns**

13. Herpes infection during the newborn period (neonatal herpes) is a relatively rare occurrence, but one that can cause severe, life-threatening infection. The majority (85%) of babies infected with herpes during the newborn period become infected when a woman with genital herpes (due to HSV-1 or HSV-2) transmits the infection to her baby as the baby passes through the birth canal. Because neonatal herpes is so serious, the American College of Obstetrics and Gynecologists recommends that cesarean section delivery be performed if a pregnant woman has any signs of genital herpes at the time of delivery.<sup>2</sup> Another 5% of babies with neonatal herpes acquire herpes infection from their mothers before delivery, while still in the uterus ("congenital infection"). Only 10% of all babies with neonatal herpes become infected after birth ("postnatal infection").

14. Most pregnant women with herpes infection, whether HSV-1 or HSV-2, transfer antibodies against HSV through the placenta to the baby; this "maternal antibody" generally protects the baby from developing herpes, even if they are exposed to the virus after

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<sup>2</sup> For a reference, see, "Management of Genital Herpes Simplex Virus Infection During Pregnancy," American College of Obstetricians & Gynecologists Practice Bulletin No. 82 (2007).

birth. See Brown Z.A., Wald A., Morrow R.A., Selke S., Zeh J., Corey L., “Effect of Serologic Status and Cesarean Delivery on Transmission Rates of Herpes Simplex Virus from Mother to Infant,” *Journal of American Medical Ass’n*, (2003), at 203-9, annexed hereto as Exhibit “E.” Babies born to women who do not have herpes infection lack protective maternal antibody and are, therefore, at high risk for herpes infection if exposed to herpes virus after birth. In New York City, 73% of women of child-bearing age have some antibody to HSV-1, so most newborns have some protection from HSV-1 infection if exposed during, or after birth. This explains why the incidence of neonatal herpes is low, even though most women are infected with the virus.

15. Neonatal herpes infection can be serious and life-threatening because newborn infants do not have fully developed immune systems. Approximately one in five newborns with neonatal herpes dies from their infection. In some cases, infection is limited to the skin, eyes, or mucous membranes; however in more than half of cases, herpes infection spreads to involve the brain (central nervous system herpes infection), or to the entire body, resulting in multiple organ failure (disseminated herpes infection); herpes blisters may be seen in all forms of neonatal herpes. Babies that survive herpes infection often have brain damage.<sup>3</sup> The incubation period for neonatal herpes infection (time from exposure to illness) varies, depending on the form the disease takes in the newborn. Most newborns with herpes infection limited to the skin, eyes, or mucous membranes, or with central nervous system infection, present to medical attention at 10-12 days after birth, when exposure most often occurs. When the disease

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<sup>3</sup> Kimberlin D.W., Lin C.Y., Jacobs R.F., Powell D.A., Frenkel L.M., Gruber W.C. and the National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group, “Natural History of Neonatal Herpes Simplex Virus Infections in the Acyclovir Era, *Pediatrics* (2001), at 223-9.



is disseminated, it presents later, usually 16-19 days after birth. A copy of Kimberlin D.W., "Neonatal Herpes Simplex Virus Infection," *Clinical Microbiologic Reviews* (2004), is annexed hereto as Exhibit "F." In New York City, approximately 75% of babies with neonatal herpes develop illness within 14 days of birth. A copy of Handel S., Klingler E.J., Washburn K., Blank S., Schillinger J.A., "Population-Based Surveillance for Neonatal Herpes in New York City, April 2006-September 2010," *Sex Transm Dis.* (2011), at 705-11, is annexed hereto as Exhibit "G." Because herpes infection can be so severe in newborns, all infants suspected of having herpes should be hospitalized immediately and treated with intravenous antiviral medication for at least 14 days.

16. Neonatal herpes is a rare infection in New York City. There are only about 15 cases each year, among approximately 125,000 live births. In New York City, neonatal herpes infection is much more common among babies born to women who are Black or Hispanic; only 25% of herpes infected babies are born to white non-Hispanic women. See Exhibit "G." About half of neonatal herpes infections are due to HSV-1 and half due to HSV-2.

**A Ritual Jewish Circumcision Practice Known as *Metzitzah B'peh* has a Long History of Transmitting Infectious Diseases to Newborn Boys**

17. Jewish circumcision is traditionally performed on the eighth day of life by a ritual circumciser (*mohel*), although circumcision may be delayed if the infant is ill. Some ritual circumcisions include a practice known as *metzitzah b'peh*, wherein the *mohel* places his mouth directly on the newly circumcised penis to suck blood away from the circumcision wound ("direct oral suction"). For the remainder of this Declaration, the term "ritual circumcision" will be used to refer to circumcision performed in a non-hospital setting by a *mohel*, and the term "direct oral suction" will be used to refer to the practice of placing the mouth directly on the penis to suck blood away from the circumcision wound. Direct oral suction is practiced by *mohelim* (plural of *mohel*) belonging to some Orthodox Jewish sects. Some *mohelim* will



perform direct oral suction on babies they are circumcising even if the infant's family are not members of their sects.

18. It has long been established that diseases can be transmitted through direct oral suction. Beginning in the 1800's, numerous scientific publications have documented disease transmission from the adult mouth to the infant penis — specifically, tuberculosis of the infant penis and syphilis of the infant penis following direct oral suction in the United States and Europe. There have been at least 72 cases of tuberculosis of the penis following ritual Jewish circumcision documented in the English language scientific literature. See Sprecher S., "Mezizah be-Peh—Therapeutic Touch or Hippocratic Vestige?" *Hakirah* (2006); Holt E., "Tuberculosis Acquired Through Ritual Circumcision," *Journal of American Medical Ass'n*, (1913); and Lewis E., "Tuberculosis of the Penis; A Report of 5 New Cases," *Journal of Urology* (1946), at 737-45, collectively annexed hereto as Exhibit "H."

19. In 1873, the New York City Board of Health commissioned an investigation into a cluster of 4 infants with serious infection (3 of whom died) following direct oral suction conducted by a single *mohel* in NYC, although the infecting agent was not definitive in those cases. See Taylor R.W., "On the Question of the Transmission of Syphilitic Contagion in the Rite of Circumcision," *New York Medical Journal*, (1873), at 561-582, annexed hereto as Exhibit "I."

20. Tuberculosis and syphilis are now uncommon in the adult population of the United States, and tuberculosis and syphilis of the infant penis are no longer seen in this country. Over time, as both the medical profession and many religious leaders recognized the risk for serious infection and death following direct oral suction, many religious groups have largely abandoned the practice. See *Hakirah* publication, Exhibit "H." Nevertheless, DOHMH continues to receive sporadic reports of serious bacterial infection following direct oral suction.

**Direct Oral Suction and Neonatal Herpes Infection**

21. Neonatal herpes infection following direct oral suction has been reported multiple times in the medical literature. Between 2000 and 2004, there were three reports published: (1) Rubin L, Lanzkowsky P., "Cutaneous Neonatal Herpes Simplex Virus Infection Associated with Ritual Circumcision," *Pediatric Infectious Disease Journal* (2000), at 266-8; (2) Distel R., Hofer V., Bogger-Goren S., Shalit I., Garry B.Z., "Primary Genital Herpes Simplex Infection After Jewish Ritual Circumcision," *Israel Medical Association Journal* (2003), at 893-4.; and (3) Gesundheit B., Grisaru-Soen G., Greenberg G., "Neonatal Genital Herpes Simplex Virus Type 1 Infection After Jewish Ritual Circumcision: Modern Medicine and Religious Tradition," *Pediatrics* (2004), at 259-63, collectively annexed hereto as Exhibit "J." Together, these three reports describe a total of 11 babies, two in NYC (from 1988 and 1998), one from Canada, and eight from Israel. All of the babies were infected with HSV-1, all had blisters on the genitals suggesting that herpes virus was introduced at the genitals, and individual *mohelim* had performed direct oral suction on two of the HSV-infected babies each.

22. The DOHMH investigation described in the June 8, 2012 CDC Morbidity and Mortality Weekly Report ("MMWR"), "Neonatal Herpes Simplex Virus Infection Following Ritual Jewish Circumcisions that Included Direct Orogenital Suction – New York City, 2000 - 2011, published June 2012, annexed hereto as Exhibit "K," adds 11 more cases to the medical literature, bringing the total number of cases of neonatal herpes following direct oral suction reported in the medical literature to 22 (13 from NYC).

23. The number of cases reported in the medical literature must be considered a minimal estimate of the actual occurrence of neonatal herpes following ritual circumcision with direct oral suction because: (1) it is likely some cases of neonatal herpes following ritual circumcision were not recognized as being related to direct oral suction; and (2) in only a

fraction of recognized cases would health care providers go to the lengths of thoroughly investigating, writing, and submitting an article for publication in the peer-reviewed medical literature.

**DOHMH Investigation of a Cluster of Neonatal Herpes Cases Following Direct Oral Suction by a Single Mohel in New York City in 2004.**

24. Important evidence linking direct oral suction to neonatal herpes comes from a cluster of 3 laboratory-confirmed<sup>4</sup> cases that were linked to a single *mohel*; these cases are detailed among the 11 cases reported in the MMWR (see Exhibit “K,” Cases 2, 3, and 4 in Table 1 and the Figure). In November, 2004, DOHMH was notified by two New York City hospitals that a set of twin male infants (“the 2004 twins”) born in early October 2004, had been hospitalized and diagnosed with disseminated HSV-1 infection, and that the first male twin (Twin A) had already died from the infection. DOHMH was also informed that before becoming ill, the 2004 twins had undergone ritual circumcision by Mohel A and that both of the circumcisions had included direct oral suction. DOHMH then also learned a baby born in 2003 had also developed HSV-1 infection at the penis day after being circumcised by Mohel A. Initially, Mohel A admitted that he performed direct oral suction during all three circumcisions.<sup>5</sup>

25. For each of the three cases, DOHMH investigated possible routes by which herpes infection could have been transmitted to the infants, including: (1) transmission from mother to baby before or during delivery; (2) transmission from hospital staff to baby during the hospital nursery stay; (3) postnatal transmission from the mother or other caretakers to

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<sup>4</sup> Laboratory-confirmed infection is defined as detection of virus (e.g., by culture) in a specimen from the infant.

<sup>5</sup> Mohel A would later deny performing direct oral suction on the baby born in 2003. In addition to his initial statement, however, he was also witnessed performing the procedure on that child.

baby in the newborn period either before or after circumcision; and (4) transmission from the *mohel* to the infant during circumcision. For these investigations, DOHMH interviewed outpatient and inpatient physicians responsible for caring for the infants, and the infants' parents and other caregivers. DOHMH also obtained and reviewed the following medical records and reports, including all available laboratory tests:

1. Mothers' outpatient prenatal medical records;
2. Mothers' labor and delivery records, and inpatient records from the postpartum stay;
3. Newborn infant inpatient medical records from the birth admission;
4. Newborn outpatient medical records from visits to pediatrician or specialists after birth but before admission to the hospital; and
5. Inpatient hospitalization records for the infant when hospitalized for herpes infection.

26. During these investigations, DOHMH also consulted extensively with leading national experts in herpes viruses and specifically, in neonatal herpes. Mohel A was tested for herpes virus and was found to have HSV-1 antibody, indicating infection. Although specimens were collected from his mouth on one occasion, no virus was detected. This, however, is to be expected, as viral shedding is intermittent, as discussed above, and difficult to detect by only periodic testing.

**Direct oral suction performed during ritual circumcision was determined to be the most likely source of herpes infection for all three babies**

27. DOHMH concluded from its investigation that all three infants had acquired herpes infection from direct oral suction performed by Mohel A during circumcision.

The details of these investigations are described in the June 8, 2012 MMWR. Exhibit "K." This conclusion was based on the following evidence: (1) herpes blisters were present on the genitals of all three babies,<sup>6</sup> consistent with herpes infection being introduced at the genitals in each case; (2) the timing of each infection (7-10 days after circumcision) was consistent with it being introduced at the time of circumcision; (3) the babies were infected with HSV-1, which is common in the mouth of adults; (4) the *mohel* who performed the circumcisions was infected with HSV-1 and used his mouth to suck blood away from the babies' circumcision wounds; (5) given the rarity of neonatal herpes, it was extraordinarily improbable that one *mohel*, due solely to chance, would have circumcised three babies who happened to develop neonatal herpes; and (6) alternative explanations for how the babies could have become infected were unlikely.

Transmission from mother to baby before or during delivery was unlikely for all three babies.

28. The mother of the 2003 baby had no history of oral or genital herpes and there were no genital herpes lesions present at the time of vaginal delivery. She was tested 26 days after her baby's birth and not found to have any antibodies to HSV. It is, therefore, exceedingly unlikely that she was the source of her baby's infection. The mother of the twins had no history of oral or genital herpes, and neither oral nor genital herpes lesions were present at the time of her delivery. She was not tested for herpes during her pregnancy. However, the twins were born by cesarean section (performed because of breech presentation and twinning), and cesarean delivery strongly protects against the acquisition of neonatal herpes infection. See Exhibit "E." Also, the membrane that separates mother from baby was only ruptured at the time of the cesarean section surgery; therefore, the infants had no exposure to the mother's genital

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<sup>6</sup> The 2003 baby also had herpes blisters on his back, buttocks, and foot, which are areas dermatomally related to the genitals by the nerves serving the genitals, and is therefore consistent with infection being introduced at the genitals.

tract microorganisms before or during delivery (i.e., no exposure to HSV-1, if the mother had genital infection). The twins' placenta was also examined by the surgical pathology department at the hospital where they were born; no evidence of herpes infection was found. Approximately one month after the twins became ill, the mother was tested. At that time, she had antibody to HSV-1, indicating infection.

It is very unlikely that hospital staff transmitted herpes to the three babies

29. First, the twins and the 2003 baby were born at 2 different hospitals, so the unlikely event of hospital transmission would have had to occur three times, at two different hospitals. Second, modern day standards of infection control in health care settings make it highly improbable that a hospital staff member could transmit herpes to a newborn infant. Even before the introduction of "universal precautions" in the 1980's, transmission of herpes in a hospital setting was a very rare event. Third, the policies and procedures in place at the two hospitals where the three infants were born dictate that nursing staff observe universal precautions and wear gloves when changing infant diapers. In part, universal precautions refer to the routine use by health care workers, of personal protective equipment such as gloves, facemasks, and gowns to prevent contact with blood or bodily fluids. Fourth, at both hospitals, policies and procedures require assessment of employees with possible herpes illness. At one hospital, any employee with an infectious condition would be removed from patient contact; at the other hospital, any employee with hand sores suggestive of herpes infection would be removed from patient contact. Fifth, none of the staff who had contact with the babies during their birth admission (13 staff had contact with the 2003 baby, and 14 staff had contact with the 2004 twins) had evidence of having had herpes infection during the babies' hospital stay or at any time in the previous two years. Sixth, there was no evidence found of clusters of neonatal herpes cases among babies born at the two hospitals. Hospital staff were not tested for HSV



antibodies, because it would be reasonable to expect that, on average, 73% of employees would have antibody to HSV-1, and the routine use of gloves and adherence to universal precautions while handling infants is adequate to prevent transmission.

It is unlikely that the mothers or other caretakers transmitted herpes to the babies after delivery (either before or after circumcision)

30. Postnatal transmission of herpes to newborns is extremely rare, and would be expected to occur only 1-2 times each year in New York City. It would be highly unusual for a mother to be the source of infection acquired after delivery because the babies of mothers with HSV-1 infection are protected against infection by the transfer of maternal antibody across the placenta. The protective effect of maternal antibody lasts for several months after birth, and is a critical defense against infection. If postnatal infection by mothers was a real risk, then there would be thousands of cases of neonatal herpes transmitted postnatally each year in New York City, where 73% of women of child-bearing age have HSV-1.

31. The mother of the 2003 baby was the only caretaker for the infant before and after the infant's circumcision, and she had laboratory testing which showed that she did not have herpes infection. Three people took care of the 2004 twins after they came home from the hospital (both before and after the circumcision): the mother, the maternal grandmother, and a "baby nurse." None of these people had a known history of oral herpes, and none had any signs or reported symptoms of oral herpes during the time they were caring for the infants. After the circumcision, either the mother or the baby nurse performed dressing changes on the circumcision wound with every diaper change. The baby nurse said that she never touched the circumcision wound site with her hands and that she never put her mouth on the twins' genitals or diaper area.

Subsequent Reports of Babies with HSV-1 Neonatal Herpes Following Direct Oral Suction

32. In 2005, the year following recognition of the cluster of three cases linked to a single *mohel*, there were two additional cases reported to DOHMH. See Exhibit “K” (Cases 5 and 6 in Table 1). These cases at first appeared unusual because the infants did not develop herpes blisters until much later in life than most babies with neonatal herpes. However, upon investigation, DOHMH learned that these infants had ritual circumcision weeks after birth (3 weeks after birth in one case, and 6 weeks after birth in the other), and that the interval between ritual circumcision and developing herpes on the genitals (7 days after circumcision for each child) for these babies was the same as that observed among other babies with neonatal herpes following ritual circumcision performed on the 8<sup>th</sup> day after birth. This remarkable consistency in the timing of infection following circumcision provides further support for a causal association between ritual circumcision and neonatal herpes. Id.

33. Also in 2005, DOHMH conducted a retrospective review of infants discharged from NYC hospitals, and identified another case of neonatal herpes in a male infant following ritual circumcision. Like the other cases, this baby had HSV infection on his genitals. See Exhibit “K” (Case No. 1, Table 1).

34. Since 2006, DOHMH has routinely tracked all neonatal herpes cases in the general population. In April 2006, neonatal herpes was added to the list of conditions for which reporting is mandated by the NYC Health Code (New York City Health Code § 11.03(a). Reporting was mandated for numerous reasons, including the need to establish the baseline frequency of neonatal herpes so that future potential interventions to prevent cases, such as vaccine, could be evaluated.

35. The Health Code requires that laboratories detecting HSV in specimens from infants 60 days and less must report those results to the DOHMH, and requires health care

providers to report diagnoses of neonatal herpes to DOHMH, regardless of whether or not laboratory testing has confirmed the infection.

36. DOHMH investigates all reported neonatal herpes cases by reviewing the mother's labor and delivery records and the baby's inpatient medical records, as well as interviewing health care provider(s) responsible for caring for the case. DOHMH staff collect extensive information, including male circumcision status, and the setting in which circumcision occurred. For male babies with HSV-1 or untyped HSV infection circumcised outside of a hospital setting, DOHMH attempts to interview parents to determine when symptoms of illness appeared, when circumcision was performed, and whether the circumcision included direct oral suction. If the first signs of infection occurred after circumcision, and circumcision was performed outside of a hospital setting, DOHMH staff also ask the name and address of the circumcisor so that the DOHMH can inform him that an infant he circumcised developed herpes infection, ask him to get herpes antibody testing, and advise him to avoid the practice of direct oral suction until testing is complete.

#### **General Findings of Routine Neonatal Herpes Surveillance in NYC, 2006 – 2011**

37. Routine public health tracking (surveillance) for neonatal herpes provides valuable information on the frequency with which neonatal herpes occurs in the general population of NYC, as well as the frequency with which neonatal herpes infection is caused by HSV-1 compared to HSV-2, the timing of infection, and other characteristics of the infections.

38. Between April 2006, when routine reporting of neonatal herpes was mandated in NYC, and December 2011, there were 84 cases of laboratory confirmed neonatal herpes infection reported in NYC. Fifty-four percent (54%) of cases (45/84) were among males. Among the 45 male cases, 22 were due to HSV-1, and 15 were due to HSV-2; and a total of 8

were untyped HSV. Among the 39 female cases, 15 were due to HSV-1, and 18 were due to HSV-2; a total of 6 were untyped.

39. DOHMH has routinely attempted to obtain information from the parents of newborns with HSV following ritual circumcision but has encountered significant challenges in this effort. Parents of many (but not all) of the cases with HSV-1 or untyped HSV following ritual circumcision have been members of communities that practice direct oral suction. Since 2005, the parents of many of the infected children have generally been unwilling to answer questions asking about whether direct oral suction was performed, or to supply information about where or by whom the circumcision was performed. In such cases, DOHMH considers that direct oral suction is “probable.” Direct oral suction is considered “confirmed” if parents have stated that direct oral suction was performed.

40. Among the 22 male babies with HSV-1 and 8 with untyped HSV infection, there were 5 (17%) that developed infection following ritual circumcision with either confirmed or probable direct oral suction. Additionally, there were 5 other male babies clinically diagnosed with neonatal herpes after ritual circumcision with confirmed or probable direct oral suction. These 5 other cases were not included in the June 8, 2012 MMWR because that report included only laboratory-confirmed cases.

**The Five Babies With Neonatal Herpes Due To HSV-1 Or Untyped HSV Following Ritual Circumcision, That Were Infected During 2006-2011**

41. Among the 5 laboratory-confirmed cases where neonatal herpes infection following ritual circumcision was laboratory-confirmed, one baby died from HSV-1 infection (see Exhibit “K,” ‘the Sept 2011 baby’, Case 11 in attached Table 1 and Figure. In every one of the 5 cases (Exhibit “K,” Cases 8, 9, 10, 11, Table 1, Figure), herpes blisters appeared on the skin of the genitals and or areas served by the same nerve, or closely related nerve

(dermatomally-related areas), and the infants became ill after the circumcision (MMWR, Figure). The 5 cases included two cases of HSV-1 in brothers who were circumcised 3 years apart by the same *mohel* (Mohel X). Direct oral suction was confirmed for 2 babies and was probable for the other three (which included the two brothers). Among the 5 cases, one baby had untyped HSV infection and the remaining four cases were infected with HSV-1.

**Since 2006, All the Cases of Laboratory-Confirmed Neonatal Herpes Infection Following Ritual Circumcision with Direct Oral Suction Have Clustered in Nearby Residences in Brooklyn, with 4 out of 5 in the Same Zip Code.**

42. All five of the cases following ritual circumcision lived near by one another in Brooklyn, and the four HSV-1 cases all lived in Borough Park, Brooklyn. The four HSV-1 cases accounted for 18% of the 22 cases of male HSV-1 neonatal infection in NYC during the time period: Yet the residents of the zip code in which they reside account for only 2.5% of all live male births among NYC residents. The concentration of male neonatal herpes cases with infection on the genitals in a single Borough Park zip code, and the disproportionate contribution of the residents of that zip code to the citywide burden of neonatal herpes disease, suggests a route of exposure unique to male infants in that part of Brooklyn.

43. The absence of even a single female infant with neonatal herpes infection in the same Brooklyn neighborhood further suggests an exposure unique to males. During the time period of April 2006-December 2012, there were no females with neonatal herpes (neither HSV-1 or HSV-2, nor untyped) reported from the zip code where there were 4 male HSV-1 cases. Even expanding to the larger neighborhood (comprised of 4 zip codes), or looking at the adjoining neighborhoods, there were no female cases. This suggests that genital herpes is not common among women of childbearing age in the neighborhood where the HSV-1 male cases reside, and points to a unique exposure to HSV that is occurring only among male neonates.

**It is very unlikely that the two brothers with neonatal herpes were both infected by someone in their household.**

44. Despite the plaintiffs' suggestion to the contrary, it is very unlikely that the brothers who developed neonatal herpes in 2008 and 2011 (Cases 8 and 10 in Table 1 and the Figure from the MMWR, Exhibit "K") were both infected by someone in their household. First, both boys had herpes blisters on their genitals, suggesting that infection was introduced at the genitals. Second, both boys developed herpes after ritual circumcision (7 days after circumcision [15 days after birth] for the first baby, and 9 days after circumcision [17 days after birth] for the second baby). Third, if transmission from a household contact were common for this rare infection, pairs of infected siblings would be commonly seen. In fact, other than this pair of siblings, there have been no other pairs (and no twins) with neonatal herpes in more than 6 ½ years of routine neonatal herpes surveillance in New York City. Furthermore, we could find no reports of sibling pairs (including twins) with neonatal herpes in the scientific literature. The occurrence of this rare infection in two brothers points to the *mohel* as the most likely source of HSV-1 infection. The parents reported that the brothers were circumcised by the same *mohel*. And, although the parents would not confirm that direct oral suction was done, they did acknowledge that it was reasonable to assume that direct oral suction would be performed for a male infant in their community.

**It is very unlikely that the September 2011 baby was infected by an older sibling.**

45. The 2011 baby had an older sibling with a history of oral herpes infection, however, it is unlikely that sibling was the source of the baby's infection, despite plaintiffs' suggestion that the baby contracted herpes from his older brother's pacifier. If there were contact with a sibling, it is difficult to imagine a scenario where a very young child would have had contact with the genitals of his newborn baby brother. Even if an older sibling with oral



herpes infection were to take a pacifier from his own mouth and put it into the mouth of the baby, this would not result in the baby developing herpes blisters on his genitals.

**Quantification of the Risk for Neonatal Herpes Associated with Direct Oral Suction**

46. A rate ratio is an epidemiologic “measure of association” that is used to quantify the relationship between a particular exposure and a particular outcome (or disease). A rate ratio compares the disease rate in a population that has an exposure of interest to the rate of disease in a population that does not have the exposure of interest. A rate ratio of 1.0 suggests a disease rate is no greater in the population with the exposure than it is in the population without the exposure. A rate ratio of greater than 1.0 suggests that there is a relationship between the exposure and the outcome, or disease. See also accompanying Declaration of Dr. Andrew Gelman.

47. To measure the risk for neonatal herpes associated with direct oral suction, DOHMH calculated the rate of HSV-1 or untyped neonatal herpes infection among the population of male babies likely to have had direct oral suction in infancy (“exposed”). This was compared to the rate of HSV-1 or untyped neonatal herpes infection among the population of male babies unlikely to have had direct oral suction in infancy (“unexposed”). The ratio of the rates (disease rate among the exposed, divided by the disease rate among the unexposed) is referred to as the “rate ratio.” Under-counting cases of neonatal herpes following direct oral suction will falsely reduce the rate of neonatal herpes among babies exposed to the practice and will lower the ratio between exposed and unexposed, thus reducing the strength of the relationship measured by the rate ratio. Inflating the size of the population exposed to direct oral suction will also falsely reduce measures of the relationship between direct oral suction and neonatal herpes by reducing the rate of neonatal herpes among exposed babies, thereby making it more similar to the rate in the unexposed population.

48. Rate ratios and other measures of association where only a subset of the population is sampled and used to estimate a finding for the entire population are subject to random variation in the form of sampling error. Therefore, confidence intervals are conventionally provided to estimate the potential discrepancy between the “true” population parameters and observed associations based on samples. Even health events that are based on a complete accounting of the entire population, such as in our surveillance for neonatal herpes, are subject to some degree of random variation (chance), and confidence intervals provide us an estimate of the precision of the results. A 95% confidence interval around the rate ratio indicates the range of values within which the “true” value of the rate ratio is expected to occur (with 95% probability). The result for the rate ratio is statistically significant if its confidence interval does not cross 1.0.

49. There are no published estimates of the number of male infants who have direct oral suction performed each year. In 2005, David Zweibel, Executive Vice President for Government and Public Affairs for plaintiff Agudath Israel of America, detailed an estimate of the size of the NYC population exposed to direct oral suction in a letter to DOHMH Commissioner of Health Dr. Frieden. A copy of the March 4, 2005 letter is annexed hereto as Exhibit “L.” In his letter, Mr. Zweibel proposed using Orthodox Jewish school student enrollment figures to estimate the size of the population of male children, and stated an assumption that direct oral suction would have been performed for all children enrolled in Hassidic Day Schools, half of children enrolled in Yeshiva Schools, and none of the male children in Modern Orthodox schools. His estimate was that 25,675 boys in Kindergarten-12 grade in 2005 would have had direct oral suction, or 1,975 per year on average. Exhibit “L.”

50. In the MMWR, DOHMH estimated the size of the population likely exposed to direct oral suction using Mr. Zweibel’s approach. First, the number of young male

children enrolled in Kindergarten (full and half-day) in Orthodox Jewish Day Schools in NYC was obtained from data provided by the NY State Department of Education for 2010-2011 (the most recent year available) (available at <http://www.p12.nysed.gov/irs/beds> (last accessed June 4, 2012)).

51. DOHMH estimated the proportion of New York City students in Orthodox Jewish Day Schools who are in Hassidic and Yeshiva schools using a "Census of Jewish Day Schools in the United States" which is regularly issued by the Avi Chai Foundation, a Jewish organization. The most recent available census data reported show that 43% of students in Orthodox Jewish Day Schools in New York City are in Hassidic schools and 29% of students are in Yeshiva schools – with the remaining 72% in other types of Jewish Day Schools. A copy of a publication by Schick, M., "A Census of Jewish Day Schools in the United States, 2008-2009," *The Avi Chai Foundation* (2009)(available at <http://avichai.org/wp-content/uploads/2010/06/Census-of-JDS-in-the-US-2008-09-Final.pdf> (accessed October 25, 2012)), is annexed hereto as Exhibit "M." Those proportions were applied to the number of New York City male students in full and half day Kindergarten obtained from New York State (6,197) to estimate the number of Kindergarten boys at Hassidic and Yeshiva Schools in New York City (2,665 at Hassidic, and 1,797 at Yeshiva schools). The assumptions Mr. Zweibel provided (that 100% of 2,665 Hassidic males, and 50% of 1,797 (or 899) Yeshiva males would have been exposed to direct oral suction at the time of circumcision) were applied to that figure to calculate the number of males likely exposed to direct oral suction during ritual circumcision each year (a total of 3,564 male babies). Over the 5.75 year period that the DOHMH routinely tracked neonatal herpes cases, this would be an estimated 20,493 male babies.

52. Using these numbers, and NYC vital records data for the number of live male births in NYC during that interval, DOHMH estimated the rate of neonatal herpes with

HSV-1 or untyped infection to be 24.4 per 100,000 among male babies likely exposed to direct oral suction. This rate was derived from the 5 cases that were reported, among an estimated 20,493 male babies. During the same period, there were 25 cases of HSV-1 or untyped HSV infection among the 352,411 male babies born in New York City who were unlikely to have had direct oral suction, resulting in a rate of 7.1 per 100,000 live male births. When these two rates are compared, they yield a rate ratio of 3.4, i.e., male babies likely exposed to direct oral suction have a 3.4 times higher likelihood of developing neonatal herpes due to HSV-1 or untyped HSV infection than male babies that have likely not had direct oral suction performed. A rate ratio of 3.4 is considered strong evidence of a relationship between an exposure and an outcome. The 95% confidence interval was calculated to be 1.3-9.0, indicating that it is statistically unlikely (<5% chance) that the association between direct oral suction and neonatal herpes is due to chance.

53. In the case of rare events distributed randomly across time, confidence intervals may also be calculated by using another equation: the exact conditional method using the Poisson ("P") distribution, rather than a normal distribution. The rate ratio arrived at using this method is also 3.4 and is also statistically significant using this method, with a 95% confidence interval of 1.2-6.0.

#### **Why Neonatal Herpes Following Direct Oral Suction is Not More Common**

54. For herpes transmission to occur during direct oral suction, a "perfect storm" must exist; a *mohe* must have virus present in his mouth as the time he performs direct oral suction, and the baby must be vulnerable to HSV infection. Since people with oral herpes infection shed herpes virus from the mouth only intermittently, exposure to virus may occur at only a fraction of circumcisions where direct oral suction is performed. Even if HSV is present

in a *mohel's* mouth at the time of direct oral suction, infection may not occur because most babies will have protective maternal antibodies to HSV-1 from their mothers.

**Strategies for Reducing the Risk for Herpes Transmission While Continuing to Do Direct Oral Suction are Unproven, and the Continuing Occurrence of Cases Indicates that Such Strategies are Ineffective, Inconsistently Applied, and/or Incorrectly Applied.**

55. Plaintiffs suggest that certain measures can be taken with the hope of reducing the risk for HSV transmission during direct oral suction. Such putative measures include the *mohel* abstaining from direct oral suction if any symptoms of HSV infection such as cold sores are present, rinsing with an antiseptic shortly before performing direct oral suction, and minimizing the duration of contact with the circumcision wound to one second.

56. Although these risk reduction measures may have intuitive appeal, none of the risk reduction measures suggested by Plaintiffs have been shown to reduce herpes transmission via direct oral suction. To the contrary, there are a multitude of scientific studies showing that herpes virus is present in the mouths of people who have no symptoms of oral herpes infection (see “Asymptomatic Shedding of HSV in Oral Cavity,” Exhibit “A”), and may be found equally often in the mouths of people who do and do not have symptoms. See Da Silva L.M., Guimaraes A.L.S., Victoria J.M.N., Gomes C.C., Gomez R.S., “Herpes Simplex Virus Type 1 Shedding in the Oral Cavity of Seropositive Patients,” *Oral Diseases* (2005), annexed hereto as Exhibit “N.”

57. Moreover, cases of neonatal herpes following direct oral suction have continued to occur in both NYC and NYS despite such risk reduction efforts purportedly being undertaken by *mohelim*. The fact of continued cases can be interpreted in a number of different ways: (1) the risk reduction strategies are not effective; (2) the risk reduction strategies are effective, but not correctly or consistently adhered to by *mohelim*; and (3) the risk reduction strategies are partially effective, so that the number of cases is fewer than would otherwise occur.

**Multiple Lines of Evidence Indicate that Direct Oral Suction was the Cause of Herpes Infection in the 11 Infants Who Became Ill Between 2000-2011 in New York City**

58. There are multiple lines of evidence and logic that indicate that direct oral suction was the source of herpes infection in 11 New York City babies between 2000-2011, including the two that died. First, the biologic plausibility of herpes transmission through direct oral suction is well established by scientific knowledge about the frequency of oral HSV-1 infection, asymptomatic viral shedding, and the opportunity for transmission of HSV-1 from the mouth to the genitals at the time of direct oral suction.

59. Second, the 11 cases had a very specific clinical presentation which suggested that infection occurred at the genitals at the time of circumcision with direct oral suction – herpes blisters on the genitals, infection with HSV-1, which is commonly found in the mouth of adults, and the timing of illness after circumcision.

60. Third, the epidemiologic evidence is compelling. There was clustering of cases of a rare infection around individual *mohelim* (Mohel A and Mohel X) indicating those *mohelim* as probable sources of exposure, geographic clustering of male cases and a paucity of female cases (suggesting a defined population is at risk and an exposure which is unique to males), cases that occurred after circumcision even when circumcision was delayed for several weeks, and an elevated rate ratio.

61. Fourth, and importantly, none of the other explanations for how the infants could have become infected (e.g. in the hospital, or from family members after birth) are likely from a scientific or epidemiological perspective.

**The Epidemiologic Evidence is Adequate to Guide Public Health Action.**

62. DOHMH's investigation into the relationship between direct oral suction and neonatal herpes points to a causal relationship between direct oral suction and HSV-1 and



untyped HSV infection in males. These findings are directly supported by multiple other published scientific reports of the relationship between direct oral suction and neonatal herpes; an association that was seen in different countries on different continents. The field of public health has long-standing principles for establishing causation, which include biologic plausibility, the temporality of the association between an exposure and outcome, the specificity of the evidence, and the strength of association (rate ratio). These principles were used to establish other causal relationships such as those between smoking and lung cancer, and between unprotected anal intercourse and HIV infection, and are fulfilled for these cases as well.

63. The infants became infected after a practice that violates modern standards of infection control – to place one’s mouth on an open wound on a newborn infant’s cut penis violates all universally accepted infection control practice. Health care facilities would consider direct contact between the mouth and any open wound to be a high risk for infection and, based solely on this risk, would never permit it for the same reasons that health care facilities would never permit a surgeon to spit in a surgical wound. See Mangram A.J., Horan T.C., Pearson M.L., Silver L.C., Jarvis W.R., “The Hospital Infection Control Practices Advisory Committee. Guideline for the Prevention of Surgical Site Infection, 1999.” *Infect Control Hosp Epidemiol* (1999), at 247-280.

**Statistical Significance is Not Essential to Establish a Public Health Risk, Nor to Act to Protect the Public.**

64. There are several considerations for public health authorities in evaluating whether enough evidence exists to take action to prevent disease or protect health. To be clear, the rate ratio calculated by DOHMH, though statistically significant (as set forth above), is only one indication of the relationship between the practice of direct oral suction and neonatal herpes. This measure of association and its statistical significance only adds to the many other findings that strongly implicate direct oral suction as a risk for neonatal herpes. Combining the finding of

an elevated (large) statistically significant rate ratio with the other evidence, makes the DOHMH extremely confident that the relationship between direct oral suction and neonatal herpes was not a chance finding, but rather is causal.

65. Comparing the DNA sequences of herpes virus from both babies with neonatal herpes, and the people who performed their circumcisions with direct oral suction could be informative, but is not essential to the conclusion that direct oral suction poses a risk for herpes transmission. Comparisons have not been undertaken because families have not identified the circumcisers, or the circumcisers have not allowed themselves to be tested.

There is Consensus Among Experts that Direct Oral Suction Poses a Risk for Herpes Transmission to Neonates

66. The CDC (Exhibit “K”), the Infectious Disease Society of America (“IDSA”), the Pediatric Infectious Disease Society of America (“PIDS”), and the American Academy of Pediatrics (“AAP”), have all issued statements advising that the practice of direct oral suction poses an infectious risk to newborns and should not be done. See letters from IDSA and PIDS to Mayor Bloomberg and the AAP Technical Report on Male Circumcision, collectively annexed hereto as Exhibit “O.”

67. Moreover, the accompanying affidavits of Dr. Whitley, Dr. Kimberlin, Dr. Zenilman, Dr. Wald, and Dr. Stanberry, all leading experts in herpes virus, infectious disease, and/or pediatric infection, highlight that the science linking direct oral suction to herpes transmission risk is well-established.

DOHMH is Mandated to Protect the Health of New Yorkers.

68. As set forth above, DOHMH’s mandate is to protect the health of New Yorkers. See City Charter, chapter 22. This responsibility is most profound for NYC children, who are among the most vulnerable citizens. Neonatal herpes is a serious infection that can

result in brain damage and death. There is extensive and consistent evidence that direct oral suction poses a risk for herpes transmission to newborns. Even without a statistically significant rate ratio, this evidence is more than strong enough to compel DOHMH to take action to protect its youngest citizens.

**DOHMH's Discussions with Religious Leaders and Attempts to Educate the Public About Risks Associated with Direct Oral Suction**

Working with Leaders in the Jewish Community

69. Since early 2005, DOHMH has diligently pursued public health education and outreach about the risks associated with direct oral suction and HSV-1. Such outreach has been in the form of written communications disseminated to the Jewish population and the general population, as well as meetings between DOHMH officials and community leaders and leaders of various religious Jewish organizations, including some with the organizational plaintiffs named herein. In addition, there were meetings held with religious leaders and DOHMH, and religious leaders and the New York State Department of Health.

70. Beginning in 2005, DOHMH participated in many meetings with leaders of the Jewish community to discuss the issue of HSV-1 infection associated with direct oral suction during circumcision. Many of the meetings were led by the then-DOHMH Commissioner Dr. Frieden, and included leaders of religious organizations, such as David Zweibel of Agudath Israel, leaders of the Central Rabbinical Congress, Rabbi David Niederman, then-New York City Councilmember Simcha Felder, Rabbi Yisroel Belsky, Dr. Kenneth Glassberg, Dr. Alan Wertzberger, among others. Copies of letters memorializing some of these meetings, including lists of attendees, are collectively annexed hereto as Exhibit "P."

71. There were also other such meetings held with religious leaders, medical professionals, and the attorneys involved in the 2004 state court litigation that the City of New

York commenced against the *mohel* linked to 3 cases of neonatal herpes in order to get him to stop practicing direct oral suction in New York City.

72. In addition, on August 11, 2005, Mayor Michael Bloomberg and Commissioner Frieden met with a group of prominent rabbis and religious leaders at City Hall to discuss the issues of DOHMH's investigation into cases of neonatal HSV-1 infection connected to direct oral suction, and DOHMH's recommendation to cease direct oral suction. See "City Questions Circumcision Ritual After Baby Dies," *New York Times*, Aug. 26, 2005, annexed hereto as Exhibit "P."

73. Not only did DOHMH work directly with the religious community in an attempt to resolve some of the different points of view regarding the medical risks associated with direct oral suction, but the New York State Department of Health also met with religious leaders and DOHMH in 2005 and 2006. Ultimately, those meetings culminated in a protocol signed by the State Department of Health and various religious community leaders, outlining steps that ritual circumcisers performing direct oral suction would undertake to reduce the medical risks associated with the practice. A copy of the Circumcision Protocol Regarding the Prevention of Neonatal Herpes Transmission, signed by the New York State Department of Health Commissioner, several New York State Department of Health officials, leaders in the Jewish community, and 28 rabbis, many of whom are known leaders in the Jewish community, signed on June 12, 2006, is annexed hereto as Exhibit "Q."

74. The Protocol included facts agreed to between the State and the various rabbis about the potential for the risk of herpes transmission to newborns through direct oral suction. Specifically, it stated: "[b]ecause HSV-1 is known to be shed in saliva even while the person has no lesions or experiences no other signs or symptoms of active infection, there is a theory in some medical literature that, although extremely rare, the practice of metzizah b'peh

could be a route of transmission for HSV-1.” Exhibit “Q,” at 4. The rabbis acknowledged that HSV “is known to cause rare, but very severe infections in newborns.” Id. Moreover, the rabbis acknowledged that “[p]arents, then, should be fully informed by the Rabbis regarding this.” Id.

75. The Protocol went on to establish risk reduction strategies which would be undertaken when performing direct oral suction — steps, which DOHMH would not endorse (then or now) because the effectiveness of those precautions in preventing transmission of herpes virus during direct oral suction has not been established. It also established steps the State Department of Health will undergo in investigating cases of HSV-1 potentially caused by direct oral suction, along with acknowledgment that the persons performing circumcisions with direct oral suction would cease performing direct oral suction for either finite period in certain circumstances, or, for life, in the event of an identical DNA match between virus infecting an infant and virus infecting a *mohel*. Id.

76. Although DOHMH does not agree with all of the statements and strategies contained in the Protocol, including steps that were permitted by the State Department of Health to help prevent HSV-1 infection and the agreed-upon testing protocol to establish the scientific link between any case of HSV-1 and a particular circumciser, the Protocol is significant in that, in contrast to the present position of the plaintiffs in this litigation, rabbis and leaders in the Orthodox Jewish community acknowledged there was some medical risk associated with direct oral suction and signed onto these statements.

#### Written Public Education and Outreach

77. DOHMH’s former Commissioner Thomas R. Frieden, M.D., M.P.H., issued “An Open Letter to the Jewish Community from the New York City Health Commissioner,” dated December 13, 2005 (“Open Letter”). A copy is annexed hereto as Exhibit “R.” That letter was publicly disseminated among the general New York City population. The

Open Letter discussed DOHMH's then-recent investigations of several cases of neonatal herpes linked to a single *mohel*, and the (then) two additional cases that had occurred in the year since. The letter included factual information supporting DOHMH's conclusion that one particular (unnamed) *mohel* was the source of the 3 HSV-1 cases reported in 2004 and that the infection was a result of direct oral suction. Id. The Open Letter also informed the public that DOHMH had allowed the religious communities to address these health concerns first, allowing the rabbinical authorities to ensure that the *mohel* was to stop performing direct oral suction in New York City pending the completion of an investigation. Id.

78. Moreover, the Open Letter informed the public of DOHMH's recommendations with regard to direct oral suction, including recommendations that: (1) in advance of circumcision, parents ask persons performing ritual circumcisions on their infants ask whether there will be direct oral suction; and (2) consider asking the person performing the circumcision to use a glass tube, pipette, sponge, or gauze pad, to wipe the blood away. See Exhibit "R," at 2.

79. The Open Letter concluded with DOHMH's medical conclusions. It provides, in relevant part, as follows:

The Department has reviewed all of the evidence and there exists no reasonable doubt that *metzitzah b'peh* can and has caused neonatal herpes infection. We have always maintained that it is our preference for the religious community to address these issues itself as long as the public's health is protected. While some medical professionals and others in the Jewish community have called on the Department to completely ban *metzitzah b'peh* at this time, it is our opinion that educating the community through public health information and warnings is a more realistic approach.

Exhibit "R," at 3.

80. In connection with the Open Letter, in 2005, DOHMH prepared and distributed a fact sheet entitled "Before the Bris: How to Protect Your Infant Against Herpes



Virus Infection Caused by *metzitzah b'peh*.” The “Before the Bris” fact sheet was publicized and available through ‘311’ in English, Hebrew, and Yiddish. A copy of the “Before the Bris” fact sheet is annexed hereto as Exhibit “S.” Both the Open Letter and the “Before the Bris” fact sheet were also posted on DOMHH’s website in 2005.

81. In December 2005, DOHMH also issued “Health Alert #46: Neonatal herpes infection with herpes simplex virus type 1 following circumcision with oral suctioning (*metzitzah b'peh*). The Health Alert was distributed to New York City hospitals via the NYC DOHMH Health Alert Network (HAN) which has approximately 22,300 subscribers, which includes both individual practitioners and multi-physician medical facilities, and was specifically addressed to medical professionals in the following specialties: pediatrics (including pediatric infection diseases, neonatology, and urology), adult infectious diseases, emergency medicine, and obstetrics/gynecology. A copy of Health Alert #46, dated December 13, 2005, is annexed hereto as Exhibit “T.” The Health Alert advised medical professionals about direct oral suction, advised physicians to consider the possibility of herpes infection in male infants exhibiting certain symptoms after circumcision, to hospitalize all neonates suspected of having herpes infections, and to notify DOHMH within 24 hours of any diagnosis of neonatal herpes following circumcision.<sup>7</sup> All Health Alerts are posted on DOHMH’s website.

82. In addition, in 2010, the New York State Department of Health issued a brochure, also entitled, “Before the Bris,” which was specifically written to inform parents of the practice of direct oral suction and risk for neonatal herpes, and was distributed to all hospitals in

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<sup>7</sup> At that time, neonatal herpes was not a reportable disease in New York City. As set forth above, in 2006, DOHMH amended the Health Code to mandate immediate reporting of all herpes virus cases in neonates age 60 days or younger. See Health Code §11-03(e).

New York State, including New York City hospitals, and placed on the New York State Department of Health and the DOHMH websites.<sup>8</sup>

83. Subsequently, several meetings took place between New York State Department of Health and the rabbis where the content of the brochure was discussed. Ultimately the brochure was removed from the New York State Department of Health's website (although it remained on the DOHMH website).

84. Finally, the State Health Department invited the rabbis to draft their own brochure on the topic. When the rabbis' draft brochure was provided to the New York State Health Department in 2011, it was devoid of any reference to the transmission of herpes through direct oral suction. A copy of the brochure submitted by religious leaders to the State Department of Health is annexed hereto as Exhibit "U."

85. In early 2012, DOHMH issued a new version of the "Before the Bris" brochure: "Before the Bris: How to Protect Your Baby Against Infection" ("2012 Before the Bris"). This brochure, published in both English and Yiddish, was disseminated by DOHMH to key birthing hospitals in 2012. These brochures remain in circulation today, and are posted on the DOHMH website. Copies of the 2012 Before the Bris brochure in English and Yiddish are collectively annexed hereto as Exhibit "V." The DOHMH press release announcing hospital distribution of the brochure is also annexed hereto as Exhibit "V."

86. The 2012 Before the Bris brochure sets forth the experience of DOHMH and the New York State Department of Health in documenting cases of HSV-1 infection in

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<sup>8</sup> In addition to the brochure, in 2010, the State Department of Health also distributed a document to ritual circumcisers throughout New York State, including New York City, which addressed the risk for transmitting herpes to newborns during direct oral suction and entitled "Bris Milah Made Safer."

neonates “on or around the genitals in male babies after circumcisions that included direct oral suctioning.” It further states: “[t]here is no proven way to eliminate the risk of HSV-1 infection from direct oral suctioning.” *Id.* The brochure recommends that parents consider alternatives to direct oral suctioning and ask a circumciser whether direct oral suctioning would be performed on their baby in advance of circumcision. The brochure concludes, as follows:

*Metzitzah b'peh* (direct oral suctioning), which is performed during some religious circumcisions, has been associated with transmission of herpes simplex type 1 (HSV-1) virus, the virus that causes common cold sores of the mouth. HSV-1 infection in a baby can be serious and lead to hospitalization and even death. When choosing a *moheh*, the Department of Health and Mental Hygiene recommends that parents ask if he practices *metzitzah b'peh* (direct oral suctioning) and request that direct oral suctioning not be performed.

Exhibit “V.”

87. In June 2012, DOHMH also posted on its website and disseminated a document entitled: “New York City Statement on Jewish Ritual Circumcision with Direct Oral Suctioning – *Metzitzah B'peh*.” A copy of this document is annexed hereto as Exhibit “W.”

88. Most recently, in September 17, 2012, DOHMH posted on its website a document called “Myths and Facts About Metzitzah B'peh.” A copy of the myths and facts document is annexed hereto as Exhibit “X” ([see http://www.nyc.gov/html/doh/downloads/pdf/std/mbp-myths-facts.pdf](http://www.nyc.gov/html/doh/downloads/pdf/std/mbp-myths-facts.pdf) [last accessed Oct. 11, 2012]). This document not only sets forth DOHMH’s experience with HSV-1 cases in neonates associated with direct oral suction, but also attempts to educate the public about the amendment to Health Code § 181.21 at issue herein. See Exhibit “X.”

89. For example, the document provides DOHMH’s responses to concerns and addresses specific misconceptions such as: that Health Code § 181.21 is a ban on all Jewish ritual circumcision, that it is a ban on direct oral suction during circumcision, that DOHMH is

the only medical or government body to identify the health risks of direct oral suction, that HSV is only transmitted through sexual intercourse, among other items. See Exhibit "X."

DOHMH's Assessment of the Success of its Public Education Outreach and Campaigns

90. To some extent, DOHMH has considered many of the public outreach steps taken to be successful. DOHMH is aware that members of the Orthodox Jewish community have some first-hand knowledge about the DOHMH concern regarding the practice of direct oral suction based on the receipt of multiple letters and phone calls from members of the Jewish community objecting to DOHMH's statements about direct oral suction and the risk for neonatal herpes infection. More than 70 letters objecting to DOHMH involvement were received by the DOHMH during June – August 2005, and many had almost identical text, suggesting that the letters were part of an organized letter-writing campaign. In addition, in 2005, the City's "311" service received more than 750 phone calls offering an opinion for the Mayor regarding Jewish circumcision. Moreover, in the 22 months since January 2011, there have been more than 11,000 visits (or "hits") to the Before the Bris brochures posted on the DOHMH website.

91. Additional evidence that the Orthodox community is aware of the potential risk for infection comes from numerous comments posted on Orthodox Jewish websites and blogs addressing the issue of direct oral suction and neonatal herpes. For example, the website theyeshivaworld.com (accessed November 11, 2012) has posted more than 35 articles on the topic of direct oral suction and neonatal herpes since June 2006, with more than 400 comments posted by readers. Paradoxically, some of the comments posted by readers of the articles on these websites and blogs indicate a continued lack of awareness of the practice itself, as well as its potential health consequences. A Google News search (accessed November 11,

2012) for the term “metzitzah b’peh and herpes” identifies approximately 5,500 blog homepages with both terms.<sup>9</sup>

92. DOHMH is also aware that our public outreach on the medical risks associated with direct oral suction has reached the medical community – including physicians in the Orthodox Jewish community, because we are aware that the Association of Orthodox Jewish Scientists hosted an event in February 2006, which featured a session on direct oral suction and HSV-1 infection in male babies. And, in August 2012, there was a Jewish medical ethics conference held in Connecticut that had an entire session dedicated to medical risks with direct oral suction. Brochures from the two conferences are collectively annexed hereto as Exhibit “Y.”

93. DOHMH’s public outreach succeeded in reaching other groups as evidenced by the 2005 statement of the Rabbinical Council of America (“RCA”) recommending against direct oral suction. See RCA’s statement, annexed hereto as Exhibit “Z.”

94. However, over the years since the DOHMH issued the Open Letter to the Jewish community, DOHMH has continued to receive complaints from parents after their infant had a circumcision that included direct oral suction without their prior knowledge or permission that such would occur. DOHMH received such a complaint as recently as Summer of 2012. These complaints have been reported to DOHMH in connection with cases of HSV-1 in infants

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<sup>9</sup> There has also been broad press coverage of the issue, as evidenced by the publication of well over 1400 articles on direct oral suction (identified using search term “*metzitzah b’peh*” in Google News on November 11, 2012) since DOHMH first became aware of cases in 2004. A Google Trends analysis using the key words “ritual circumcision, herpes” and “metzitzah” show that peaks in the number of Google internet searches made with those terms correlate with DOHMH activities related to direct oral suction and neonatal herpes, and related press coverage. These searches can be shown to originate from NY state, and are further evidence that DOHMH activities have led to population awareness of the practice of direct oral suction and the risk for herpes.

(the parents of two of the babies with HSV infection following direct oral suction were not aware in advance that the procedure would be performed), as well as in connection with babies who had direct oral suction but did not develop HSV infection, where parents have contacted DOHMH with concerns about the potential infectious risk to their child resulting from direct oral suction. Clearly parents continue to be taken by surprise by direct oral suction at the time of their son's circumcision.


95. Therefore, despite extensive DOHMH public education campaigns and outreach to Jewish community leaders, the Jewish community, and to the general population at large, the fact remains that NYC parents seeking ritual circumcision for their infant sons remain unaware of the practice of direct oral suction, and unaware of the risk it poses for transmitting herpes infection to newborns. The fact that between 2004 and 2011, DOHMH learned of 11 cases of laboratory-confirmed HSV-1 virus infections in male infants following circumcisions that were likely to have had direct oral suction, where ten of these infants were hospitalized, at least two developed brain damage, and two babies have died, is sufficient proof that public outreach alone is not serving DOHMH's mandate to protect the public health, a mandate that includes informing and educating the public about health risks.

96. For these reasons, the DOHMH and New York City Board of Health are thoroughly justified in seeking to inform all parents, in advance of circumcision that will include direct oral suction, about the practice of direct oral suction and the risk for herpes transmission during this practice, so that parents can have the knowledge they need to make a thoughtful and meaningful decision about whether to expose their infant to the risk of herpes infection, and its severe health consequences.



**WHEREFORE**, it is respectfully requested that the Court deny plaintiffs' request for a temporary restraining order and a preliminary injunction, along with such other relief as the Court may deem just and proper.

Dated            New York, New York  
November 15, 2012

  
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**THOMAS FARLEY, M.D., M.P.H.**